

APPENDIX 2
SUMMARY AND RESPONSE TO COMMENTS RECEIVED DURING THE SECOND NOTICE PERIOD
OF JULY 8, 2005 THROUGH AUGUST 22, 2005

COMMENT NO.	COMMENTS & AFFILIATION	COMMENT	RESPONSE
PH-1	Kristin Power Grocery Manufacturers of America	<ul style="list-style-type: none"> • Many GMA members subject to potential regulation under P65 and have on-going need for reliable means to assess their compliance with its requirements. • Proposed Regulation Too Restrictive <ol style="list-style-type: none"> 1. Subsection (a)(3) requires test result be obtained from a State certified lab. Too narrow and lacks a reasonable basis. 2. Defendant should be able to use test results from a broader range of labs, including those recognized by international bodies or federal or state agencies. Certified CA lab requirement is too stringent. Many entities that need to comply are outside of CA. Should provide that any lab certified by a state, USEPA, or a national organization authorized to issue certification, such as ANSI or NSF, can conduct the test. 3. OEHHA should recognize that affirmative lab “certification” programs are limited, and where they do exist, they often are restricted to certain chemicals and test methodologies commonly associated with air, soil, or water contamination rather than consumer product testing. 4. Annual test results obtained at labs recognized as competent by governmental agencies or international accreditation bodies should be deemed satisfactory for purposes of P65. Affirmative defense should not be restricted to tests conducted by CA certified labs. 5. Subsection (a)(1) states affirmative defense exists if the defendant properly applied a method of detection 	<ul style="list-style-type: none"> • OEHHA agrees that additional regulations in this area may be helpful to businesses and intends to pursue such proposals as resources allow, however the statute expressly places the burden of proving compliance with business. • The proposed regulation is narrowly focused on situations in which testing has been performed and the test results indicate the chemical in question has not been detected. <ol style="list-style-type: none"> 1. The proposed regulatory language has been expanded to a California or nationally certified laboratory based on this comment. 2. See response to comment above. Given that the regulation is voluntary and that Proposition 65 applies only to California, allowing a defendant to use either California or nationally certified laboratories should provide sufficient flexibility. 3. See responses above to items 1-2. 4. See responses above to items 1-2 5. The commenter is correct that the “within 12 months” time frame refers to the 12 months immediately preceding the date of the notice or

APPENDIX 2 (Continued)

COMMENT NO.	COMMENTS & AFFILIATION	COMMENT	RESPONSE
PH-1 (continued)	Kristin Power	<p>and analysis ... <i>within the year</i> prior... The “within the year” reference is ambiguous and could be argued to be limited to the 12-month period immediately preceding the date of the notice.</p> <p>6. Not all companies conduct annual testing. Requiring results from “within the year” presents potential defendants with too short a time period to be practical.</p> <p>7. Proposed regulation should be modified to permit reliance on results obtained at any time during the previous 2 or 3 years.</p> <ul style="list-style-type: none"> • Language of the Proposed Regulation Should Be Made Consistent With the Agency’s Explanation of the Rule <ol style="list-style-type: none"> 1. “Required by permit” language in subsection (c) is an improvement on the original proposal. However, more appropriate to conform the language of the proposed regulation to that which already has been set forth as the explanation of the rule. 2. If a permit exists, in addition to Statement of Reasons, regulation should make it clearer that a defendant need not enter into a determination of the “most sensitive method of detection and analysis.” 3. Affirmative permitting circumstances are limited, language of proposed regulation should be expanded to allow business to rely on a test method conducted pursuant to regulation, or governmental agency, or internationally issued guidelines as well as a “permit.” 4. Suggested revision: “(c) Where more than one method of detection and analysis exists that meets the criteria specified... the person...must either use a method of detection and analysis required by permit, 	<p>filing of the complaint as is expressly stated in the text of the proposed regulation.</p> <p>6. As noted in previous responses to comments on this issue, the one-year time frame is based on the statute of limitations period for Proposition 65 actions. A defendant may still offer evidence of testing conducted prior to one-year under the general rules of evidence.</p> <p>7. See response to item 5 above.</p> <ul style="list-style-type: none"> • The comment is noted, but OEHHA declines to expand the proposed regulation as far as suggested. In order to take advantage of the affirmative defense offered by this regulation, the defendant must use either a test method required by permit or the most sensitive test method that meets the other criteria in the regulation. To expand the provision further as suggested by the commenter would encourage a defendant to use the least sensitive of the available methodologies.

APPENDIX 2 (Continued)

COMMENT NO.	COMMENTS & AFFILIATION	COMMENT	RESPONSE
PH-1 (continued)	Kristin Power	<p>regulation, or government or international agency-issued guideline to be used for detecting or measuring the chemical in question in the relevant matrix; or in the absence of a method required by permit, regulation or government or international agency-issued guideline, the person must use the most sensitive method of detection and analysis available that meets all the criteria in subsection(b).”</p> <ul style="list-style-type: none"> • Rule as Proposed Should Apply to Plaintiffs as well as Defendants <ol style="list-style-type: none"> 1. Putting the burden solely on businesses impermissibly tries to shift the statute’s initial burden of proving an exposure from the plaintiff solely to the defendant. 2. Under proposed scheme, plaintiff bound only by “any admissible evidence” constraint proposed in subsection (e). Can hire an expert who opines that some exposure to a listed chemical is more likely than not to occur despite the absence of any data or tests. 3. To avoid further deterioration of the statutory burden of proof, text in proposed Section 12900 subsection (d) should be amended to remove doubt that to obtain its affirmative defense, a defendant is only required to prove that it has run the test that was required otherwise recognized as acceptable to a federal or state agency or international body and obtained a non-detectable result. 4. To avoid unnecessary ambiguity, sentence in subsection (d) should delete the term “proof as to all the facts that establish such defense including” and be left to read, “...the person asserting this section as 	<ul style="list-style-type: none"> • This issue has already been addressed in the prior responses to comments and does not relate to the changes to the proposed regulatory language. However, as responded to previously, the proposed regulation expressly states in subsection (e) that it does not change the existing burdens of proof for enforcement actions. Defendants always have the burden of proving the elements of their affirmative defenses; this duty is not changed by the terms of the proposed regulation.

APPENDIX 2 (Continued)

COMMENT NO.	COMMENTS & AFFILIATION	COMMENT	RESPONSE
		<p>an affirmative defense shall have the burden of proving that all material protocols and procedures...have been followed.”</p>	
PH-2	<p>Michael J. Van Zandt McQuaid, Bedford & Van Zandt on behalf of plumbing importers and distributors</p>	<ul style="list-style-type: none"> • Remained concerned with the majority of the provisions addressed in their April 18, 2005 comments. • Strongly agree with the omission of the former Section 12900(g) that permitted application of Section 12900 to any enforcement action pending at the time of the regulation’s adoption. • Section 12900 does not adequately replace or clarify the repealed Section 12901, instead creates more ambiguity and uncertainty for businesses. • Text continues to avoid designation of specific acceptable test methodologies. • Revisions have not diminished their concern the Section 12900 is far more rigorous for defendants to meet than its predecessor, specifically regarding the “non-detect” and “most sensitive method of analysis” provisions. • Revised text will not “meet the basic needs of the various stakeholders” nor will it “further the purposes of the Act.” • Omission of designated test methodologies poorly serves even the most diligent businesses by depriving them of any certainty that their attempts to comply will be validated. • Contrary to the stated goal in ISOR, Section 12900 does not “expressly provide businesses with the ability to rely on test results they have obtained using analytical test methods already in use or that are required for compliance with other regulatory programs to show that they are in compliance with Proposition 65.” • Sole purpose of a regulation such as Section 12900 should be to assist CA businesses to comply with the law. Should not turn compliance into a guessing game. 	<ul style="list-style-type: none"> • This issue has already been addressed in the prior responses to comments and does not relate to the changes to the proposed regulatory language. OEHHA believes that the proposed regulation addresses all of the main issues that were identified by stakeholders during the repeal of the former regulation (Section 12901) that can be addressed in a manner that is consistent with the intent and purposes of the Act. • Nothing in Health and Safety Code section 25249.12(a) requires the lead agency to establish testing methodologies for chemicals listed under the Act. The Act expressly places the burden of proving that an exposure does not require a warning on the business causing the alleged exposure, not with the lead agency. No changes to the proposed regulation were made in response to this comment. • It is not feasible for OEHHA to develop a regulation that would establish a specific method of detection and analysis that is appropriate for every listed chemical, in every medium and every exposure, discharge or release scenario. USEPA does provide an

APPENDIX 2 (Continued)

COMMENT NO.	COMMENTER & AFFILIATION	COMMENT	RESPONSE
PH-2 (continued)	Michael J. Van Zandt	<ul style="list-style-type: none"> • Inefficient and disingenuous to encourage businesses to conduct tests that may or may not be deemed appropriate by a court. • Section 12900 continues to encourage confusion, provide no guidance and invite lawsuits. • Lack of clarity and litigation that is likely to follow will discourage companies from conducting business in CA and will negatively impact the State’s economy. • Imperative that final text addresses these vital issues to avoid an exodus of small and mid-size businesses from CA. • The one-year time period may cause an entity to be unable to take advantage of the affirmative defense if a compliant product was tested over one year prior to being noticed or sued. Unreasonable outcome for a product that has not been altered and the test applied remains state of the art. • Unreasonable and costly for businesses to test each product annually, even if representative sampling is used. Time limit must be amended in final text version. • “Non-detect” requirement in Section 12900(a)(4) is unrealistic, fails to make any concession for products tested under conditions of normal use. Unfairly places defendants in a position of proving an absolute negative. • In order to allow defendants any opportunity to meet the elements of affirmative defense, provision must be amended to coincide with levels of detection that are above a properly established health minimum under P65. • At a minimum, for listed chemicals that OEHHA has already promulgated maximum levels of exposure, these levels should be consistent, rather than have Section 12900 create a new, absolute liability standard that no defendant will be able to disprove. 	<p>index of its approved test methods that may be useful to businesses. This is available from USEPA at the following link: http://www.epa.gov/NE/oarm/testmeth.pdf</p> <ul style="list-style-type: none"> • Businesses are in the best position to identify the most appropriate testing methodologies. The proposed regulation is simply providing an affirmative defense option for those businesses that voluntarily conduct testing to ensure compliance with the Act. • The one-year time frame is based on the statute of limitations period for Proposition 65 actions. A defendant may still offer evidence of testing conducted prior to one-year under the general rules of evidence. • This comment does not address the changes to the proposed regulation. See initial responses to comments. The proposed regulation does not require businesses to conduct product testing. It simply provides businesses that do conduct testing with an opportunity to assert an affirmative defense to an enforcement action if the chemical has not been detected. • Nothing in the proposed regulation prohibits businesses from using any test

APPENDIX 2 (Continued)

COMMENT NO.	COMMENTS & AFFILIATION	COMMENT	RESPONSE
PH-2 (continued)	Michael J. Van Zandt	<ul style="list-style-type: none"> • Section 12900(c) appears to lessen the effect of the “most sensitive method of detection and analysis” provision by allowing an alternative application under Section 12900(a), “use a method of detection and analysis required by permit [as defined in the regulation] to be used for detecting or measuring the chemical in question in the relevant matrix.” • Remain concerned because test methodologies have inherent varying degrees of precision and sensitivity, exacerbated by the fact that a single method can use multiple types of equipment to analyze raw data. Variances between tests provide an opportunity for P65 enforcers to question any test result. • Even framed as an alternative application, the “most sensitive method of detection and analysis” language should be removed from the text. • Very important to provide a compliance period. As drafted, regulation will take effect immediately and businesses that have reasonably relied upon Section 12901 will have to shift gears to make sure they remain in compliance with current law. • Must allow a reasonable period of time to bring business into compliance with new requirements. • References to “subsection (f) below” appear in Section 12900(a)(1) and (a)(2) should be changed to accurately reflect intended reference of Section 12900(g). • Replacement of term “medium” with term “matrix” is not necessary and does not serve to better define the concept at issue. 	<p>methodology they deem appropriate for a given product. The regulation is intended to provide an affirmative defense for those businesses that conduct testing using a method that has been authorized or required by one of the listed agencies. If another agency should be added to those listed, OEHHA would consider such an addition.</p> <ul style="list-style-type: none"> • Nothing in the proposed regulation limits the other provisions of the existing regulations dealing with NSRLs or MADLs. It is a narrow provision offering an affirmative defense in the event the chemical has not been detected at all. In the event the chemical is detected, the business would need to refer to these and other provisions of the regulations to determine whether a warning is required or not. • Generally, laboratory QA/QC procedures will effectively address the issues of false positive test results, background concentrations of chemicals and any need for re-sampling. These issues are outside the scope of the proposed regulation since it is intended to apply to situations in which the reported test results show that the chemical in question has not been

APPENDIX 2 (Continued)

COMMENT NO.	COMMENTER & AFFILIATION	COMMENT	RESPONSE
PH-2 (continued)	Michael J. Van Zandt		<p>detected. The issues noted should be resolved by the laboratory conducting the testing, prior to the issuance of final test results to the business.</p> <ul style="list-style-type: none"> • To remove the “most sensitive method of detection and analysis” language would encourage a defendant to use the least sensitive of the available methodologies. No changes to the proposed regulation were made in response to this comment. • Businesses are not required by the proposed regulation to take any action at all; therefore, a “compliance period” is not necessary. The affirmative defense offered by the proposed regulation is entirely voluntary. • The references noted in the comment have already been corrected in the proposed amended regulatory language. So no change has been made based on this comment. • The chemical of concern may be contained in some environmental medium or a consumer product and OEHHA believes the term “matrix” better describes and defines the substance at issue.
PH-3	John L. Wittenborn Joseph J. Green Collier Shannon Scott, Counsel to	<ul style="list-style-type: none"> • Continues to support the concept of clarifying regulations pertaining to methods of detection, reiterate March 31, 2005 comments that propose provisions arbitrarily limit the scope of test methods that may be used. 	<ul style="list-style-type: none"> • This issue has already been addressed in the prior responses to comments and does not relate to the changes to the proposed regulatory language. The

APPENDIX 2 (Continued)

COMMENT NO.	COMMENTS & AFFILIATION	COMMENT	RESPONSE
	Leathers Industries of America	<ul style="list-style-type: none"> • Subsection (b) arbitrarily and capriciously restricts the availability of acceptable test methods to those required or sanctioned by a variety of federal, state, or local agencies “with jurisdiction over the product or activity that is the cause of the discharge, release, or exposure.” • Modified language set out in July 8, 2005 notice unreasonably and quite possibly unconstitutionally requires that the laboratory conducting the testing be “certified by the State of California.” Place unnecessary and burdensome restrictions on the methods of testing companies may use, and likely will preclude the ability of many manufacturers, to utilize the new provisions. • Although established and valid scientific test methods exist for identifying the presence and concentration of various chemicals in leather goods, these methods would not meet the requirements of the proposed section because they are not “required or sanctioned” by any government agency. • New regulations may ultimately apply only to situations involving environmental releases and discharges, workplace exposures, and exposures associated with food products because of the restrictions of subsection (b). No rational basis for restricting the “safe harbor” in this manner. • Leather industry and others may be denied the affirmative defense simply because their products are not subject to testing methods required or sanctioned by a designated agency. • Even a company that subjects its products to the most exacting test protocols and follows recognized quality control and assurance procedures may be unable to avail itself of the affirmative defense. • It is the epitome of arbitrary and capricious to deny the 	<p>proposed regulation does not prohibit businesses from using any test methodology they deem appropriate for a given product. The regulation is intended to provide an affirmative defense for those businesses that conduct testing using a method that has been authorized or required by one of the listed agencies. No additional response required.</p> <ul style="list-style-type: none"> • The proposed regulation is narrowly focused on situations in which testing has been performed and the test results indicate the chemical in question has not been detected. The proposed regulatory language has been expanded to a California or nationally certified laboratory based on this and other similar comments. Given that use of the affirmative defense is voluntary and that Proposition 65 applies only to California, allowing a defendant to use either California or nationally certified laboratories should provide sufficient flexibility and does not infringe on any Constitutionally protected rights of potential defendants and does not trigger Commerce Clause issues. • The proposed regulation lists possible sources of methods of detection and analysis, some of which are local agencies that have limited jurisdiction.

APPENDIX 2 (Continued)

COMMENT NO.	COMMENTER & AFFILIATION	COMMENT	RESPONSE
PH-3 (continued)	John L. Wittenborn Joseph J. Green	<p>“safe harbor” defense to entire industries by not providing alternative testing methods when no agency-sanctioned test method is available.</p> <ul style="list-style-type: none"> • While numerous agencies have jurisdiction over environmental discharges from leather manufacturing facilities, none of the proposed agencies have jurisdiction over the actual leather products. • No agency has adopted test methods for evaluating chemicals present in leather goods. • Thus, although valid scientific test methods used by the leather industry and the Leather Research Lab are consistent with the types of methods the proposed regulations seeks to encourage, methods would not satisfy provision in subsection (b). • Proposed regulation must be amended to clarify that if no agency has jurisdiction over the product, then valid scientifically established test methods used in the industry as defined in subsection (g) might also be relied upon. (Consistent with previous Section 12901(c) and (d).) Failure to allow industry testing methods in this circumstance would be entirely unreasonable. • Reiterate concerns that regulations clarify that standard valid test methods used in an industry may be relied upon if no regulatory agency has jurisdiction over the product exposure at issue or no agency has adopted a relevant method. • Denying “safe harbor” defense to any company for which no agency has sanctioned or required test methods without regard for the adequacy of alternative testing methods impermissibly discriminates against entire industries. Unlikely to withstand judicial scrutiny. • Limitation added that requires that labs be “certified by the 	<p>These are included because they are most likely to have required or sanctioned a particular method of detection and analysis through the issuance of a permit or other official action. The regulation requires the use of the most sensitive methodology among those authorized or required <i>by the agencies listed</i>. Nothing in the proposed regulation requires a business to conduct any testing at all.</p> <ul style="list-style-type: none"> • In addition, the amended proposed regulation gives a preference to testing done under permit, even where such testing is not the most sensitive. • It is not feasible for OEHHA to develop a regulation that would establish a specific method of detection and analysis that is appropriate for every listed chemical, in every medium and every exposure, discharge or release scenario. USEPA does provide an index of its approved test methods that may be useful to businesses. This is available from USEPA at the following link: http://www.epa.gov/NE/oarm/testmeth.pdf • Businesses are in the best position to identify the most appropriate testing methodologies. The proposed regulation is simply providing an

APPENDIX 2 (Continued)

COMMENT NO.	COMMENTER & AFFILIATION	COMMENT	RESPONSE
PH-3 (continued)	John L. Wittenborn Joseph J. Green	<p>State of California” add an additional unnecessary restriction that will limit practical utility of provision. Adds an extra layer of bureaucracy to process.</p> <ul style="list-style-type: none"> • State certification will do little to enhance credibility of testing; will prevent many companies, particularly those outside CA from taking advantage of provision. • Limiting availability of the proposed affirmative defense to tests conducted by state-sanctioned labs raises serious concerns about validity of regulation under Commerce Clause of the US Constitution. • Other provisions ensure testing credibility. Person asserting affirmative defense has burden of demonstrating that “all material protocols and procedures” have been followed. (Includes all standard QA/QC requirements.) Ample opportunity to challenge credibility in court, if needed. • Leather Research Lab is the premier testing facility for US leather industry, but is not state certified. Since the purpose of regulation is to provide a “safe harbor” for manufacturers who conduct thorough scientific testing of their products, and since the quality of out-of-state labs is not in question, it is arbitrary and capricious to exclude labs that do not obtain certification. • Exclusion is unduly burdensome on manufacturers seeking to comply and undermines the goal of regulation to encourage rigorous, high-quality scientific testing of products. • Commerce Clause prohibits states from interfering with or unreasonably impeding interstate commerce. Also prohibits states from unfairly discriminating against out-of-state businesses in favor of their own businesses unless no reasonable alternatives to the discrimination are available. 	<p>affirmative defense option for those businesses that voluntarily conduct testing to ensure compliance with the Act through a laboratory certified by the State of California or a Federal agency.</p> <ul style="list-style-type: none"> • The proposed regulation is narrowly focused on situations in which testing has been performed and the test results indicate the chemical in question has not been detected. • The proposed regulatory language has been expanded to require a California or nationally certified laboratory based on this and other comments received concerning this provision of the proposed regulation. • See response to comment above. Given that the regulation is voluntary and that Proposition 65 applies only to California, allowing a defendant to use either California or nationally certified laboratory should provide both the needed flexibility and a level of confidence in the reported results. • It is not clear from the comment whether the Leather Research Lab would be conducting tests required or sanctioned by one of the federal, state or local agencies identified by the regulation. If so, the laboratory would likely also be certified, if not, the regulation would not be applicable to

APPENDIX 2 (Continued)

COMMENT NO.	COMMENTER & AFFILIATION	COMMENT	RESPONSE
PH-3 (continued)	John L. Wittenborn Joseph J. Green	<ul style="list-style-type: none"> • May run afoul of Commerce Clause because: <ol style="list-style-type: none"> 1. Access to CA-certified labs would be limited for businesses outside CA. 2. While proposed regulation does not prohibit certification of non-CA labs, there would be far fewer CA-certified labs outside the state. 3. Proposed regulation limits ability of out-of-state labs to conduct interstate business because they will be required to obtain special certification from CA. 4. Adds a cumbersome bureaucracy layer that would be completely unmanageable if other states followed CA. 5. A proposed regulation provides no certification criteria and will result in a disproportionately advantageous position for CA companies and labs. • Strongly encourage OEHHA to remove the CA state certified lab requirement from proposed text. 	<p>such tests and the defendant company would need to rely on the general provisions of the California Evidence Code to determine whether the test results would be admissible as evidence in any enforcement action.</p> <ul style="list-style-type: none"> • The National Environmental Laboratory Accreditation Program (NELAP) granted the California Department of Health Services Environmental Laboratory Accreditation Program (ELAP) to be the NELAP Accrediting Authority (AA) for California. Therefore, the California Department of Health Services ELAP certifies both the California (ELAP) and the National (NELAP) programs. • In response to this comment, the proposed regulation as currently drafted includes a provision allowing accreditation through any other similar nationally certified organization. This should allow sufficient flexibility to out-of-state businesses in selecting an appropriate laboratory to conduct testing. • See response to comment above. Given that the regulation is voluntary and that Proposition 65 applies only to California, allowing a defendant to use either California or nationally certified laboratory should provide both the

APPENDIX 2 (Continued)

COMMENT NO.	COMMENTER & AFFILIATION	COMMENT	RESPONSE
PH-3 (continued)	John L. Wittenborn Joseph J. Green		needed flexibility and a level of confidence in the reported results. OEHHA has expanded the proposed regulation to allow the use of specified non-California certified labs.
PH-4	Curt Fujii Allied Waste John McNamara CRRC Southern District Pat Sullivan SCS Engineers Peter H. Weiner Paul, Hastings, Janofsky & Walker Sean Edgar CRRC Northern District Don Gambelin Norcal Waste Systems Charles A. White Waste Management/West	<ul style="list-style-type: none"> • MDLs vs. PQLs. <ol style="list-style-type: none"> 1. Continue to believe PQL is more appropriate than using MDL in any regulatory setting as described in previous April 8, 2005 comment. 2. Understand OEHHA’s position that proposed use of MDL is appropriate for purposes of establishing a “safe harbor.” 3. Current proposed modifications of Section 12900(c) allows them to rely on “methods of detection and analysis” required by a permit should be sufficient to address majority of their concern. • False Positives and Opportunity for Verification Resampling. <ol style="list-style-type: none"> 1. Subsection (a) requires “that the results of each and every such test conducted at any time during that year show that no detectable level of the chemical in question was present.” Does not address the problem of “false-positive” sample results that may have been reported during the year. 2. OEHHA’s response to April 8, 2005 comment implies that the issue of “false-positives” is one of QA/QC. Multiple instances during monitoring at their facilities detections reported “on the record” by lab. Most turn out to be “false positive” detections that cannot be verified. 3. Once detection has been “reported” during the previous year and included in the yearlong sample 	<ul style="list-style-type: none"> • This issue has already been addressed in the prior responses to comments and does not relate to the changes to the proposed regulatory language. As stated previously, the “practical quantitation limit” may be useful in those situations in which a listed chemical is detected. However, in the event the chemical is detected, other provisions of existing regulations would need to be used to determine whether a warning is required or a discharge or release is prohibited under the Act. No additional response required. • Generally, laboratory QA/QC procedures will effectively address the issues of false positive test results, background concentrations of chemicals and any need for re-sampling. These issues are outside the scope of the proposed regulation since it is intended to apply to situations in which the reported test results show that the chemical in question has not been detected. The laboratory conducting the testing, prior to the issuance of final test results to the business, should resolve

APPENDIX 2 (Continued)

COMMENT NO.	COMMENTS & AFFILIATION	COMMENT	RESPONSE
PH-4 (continued)	Curt Fujii, et al.	<p>record, it would severely limit access to the “safe harbor” created under this regulation.</p> <ol style="list-style-type: none"> 4. Proposed regulation does not provide opportunity to verify resampling to determine if detection was valid or was a “false positive.” Only exception may be in subsection (c) that provides for methods of detection and analysis required by permit. However, permit may not provide for verification resampling procedures established in regulations or guidelines. 5. Must clearly provide opportunity for verification resampling in the event a sample is collected that shows an unexpected detection. 6. Requests that recognition of verification resampling option for environmental releases be made available under the proposed regulation. 7. Suggest the following language be added to Section 12900(a): <ul style="list-style-type: none"> ➤ <i>“(a) For purposes of Section 25249.5 of the Act no knowing discharge or release, and for purposes of Section 25249.6 no knowing and intentional exposure occurs if a person in the course of doing business, otherwise responsible for an alleged release, discharge or exposure can call all of the following:</i> <ol style="list-style-type: none"> 1. <i>That he or she has properly applied a method of detection and analysis as defined in subsection (f) below for the chemical in question at any time within the year prior to the service or filing of a notice or complaint concerning an alleged discharge, release or exposure to the chemical in question;</i> 	<p>the issue noted.</p> <ul style="list-style-type: none"> • Although OEHHA agrees with the concept that a business should be allowed to verify test results to determine if a particular test result represents a “false-positive” as described by this commenter, however, this issue does not appear to be one that should be addressed through a regulation. Further, the suggested language for inclusion in the proposed regulation contains undefined phrases such as “false-positive” that do not add clarity to the regulation. Therefore, the additional language proposed by this commenter was not included in the proposed modified text.

APPENDIX 2 (Continued)

COMMENT NO.	COMMENTER & AFFILIATION	COMMENT	RESPONSE
PH-4 (continued)	Curt Fujii, et al.	<p>2. <i>That such method of detection and analysis was applied to the same matrix as defined in subsection (f) below, in which the discharge, release or exposure is alleged to have occurred or to be occurring;</i></p> <p>3. <i>That the method of detection and analysis was conducted by a laboratory certified by the State of California; and</i></p> <p>4. <i>That all the reported results show that the chemical in question was not detected.</i></p> <p><u>Results of methods of detection and analysis that may be initially reported but which are shown to be “false-positive” detections by means of procedures established in permits, regulations or guidelines applicable to the activity shall not be considered a reported detection.</u></p> <ul style="list-style-type: none"> • Range of Applicable Tests Methods. • Believe that proposed modifications to subsection (c) satisfactorily address their concern by allowing “use of a method of detection and analysis required by the permit to be used” or other methods. Strongly request this be retained in the finally adopted version. • Interference from Background Concentrations. • Simple “detection” of constituents does not necessarily mean constituent is derived solely from a particular facility at which detection monitoring is taking place. • Proposed regulation should recognize the need for evaluation whether a detected constituent is actually the responsibility of the person conducting the detection monitoring. • OEHHA suggested that other parts of the P65 regulations 	<ul style="list-style-type: none"> • The proposed regulation is intended to apply only to those situations in which the chemical in question has not been detected. In the event the chemical is detected, other provisions of existing regulations would need to be used to determine whether a warning is required or a discharge or release is prohibited

APPENDIX 2 (Continued)

COMMENT NO.	COMMENTS & AFFILIATION	COMMENT	RESPONSE
PH-4 (continued)	Curt Fujii, et al.	<p>may address this concern. Not aware of sufficient language applicable to the Method of Detection regulations that provide assurance that detection of constituent from some other source would not be attributed to activity conducting the detection monitoring.</p> <ul style="list-style-type: none"> • Section 12501 deals only with chemicals found in Food and Section 12401 provides limited relief to public water systems, commercial sources of drinking water, drinking water sources that meet primary drinking water standards, or water that only contains “naturally occurring chemicals.” Groundwater matrix may not meet any of these if it has been contaminated by some other anthropogenic activity separate and distinct from waste management activity. • Request addition of a 5th paragraph to Section 12900(a): <ol style="list-style-type: none"> 5. <u><i>The detection does not include a discharge or release attributable to another source.</i></u> 	<p>under the Act (see for example Title 22, Cal. Code of Regs., §§ 12703 and 12801.) Differentiating background concentrations of listed chemicals from those that may be present due to the actions of a particular business are outside the scope of the proposed regulation since it is intended to apply to situations in which the final reported results show that a chemical in question has not been detected. The issue of background concentrations should be resolved by the business and laboratory conducting the testing, prior to the issuance of final test results to the business.</p> <ul style="list-style-type: none"> • OEHHA agrees that additional regulations concerning analytical testing procedures may be helpful to businesses and is open to pursuing such proposals as resources allow, however the statute expressly places the burden of proving compliance with business. • The proposed regulation is narrowly focused on situations in which testing has been performed and the test results indicate the chemical in question has not been detected. Addressing issues concerning the possibility that other sources may also be contributing to a detected test result appears to be beyond the scope of this regulation. The

APPENDIX 2 (Continued)

COMMENT NO.	COMMENTS & AFFILIATION	COMMENT	RESPONSE
PH-4 (continued)	Curt Fujii, et al.		proposed additional language provided by the commenter would not add clarity or certainty to the proposed regulation and would likely generate additional litigation concerning the extent of the contamination that might be “attributable” to another source and the various ways in which such a contribution might be established and quantified. The regulation proposed by OEHHA does not preclude a defendant from offering evidence in any proceeding that some or all of an alleged discharge, release or exposure to a listed chemical is attributable to another source.
PH-5	Andrew L. Packard on behalf of As You Sow	<ul style="list-style-type: none"> • Section 12900(a)(2), “that such method of detection and analysis was applied to the same matrix as defined in subsection (f)[sic] below...” Concerned that same kind of confusion and gamesmanship created by “specific medium” in repealed Section 12901 will arise from “same matrix” notwithstanding the definition provided in Section 12900(g). • Definition of “matrix” must be clarified to address whether a “proxy” matrix may be used in those instances when the “real world” matrix is inherently protean. “Do the proposed new [matrix] terms require that the tested matrix be the “real world” matrix into which the listed chemical is allegedly discharged even though the use of such a “real world” matrix would be scientifically invalid? Does the regulation require only a sufficiently similar matrix? How would a “same enough” standard work in the case of 	<ul style="list-style-type: none"> • OEHHA has attempted to add clarity to the proposed regulation by including a definition for the term “matrix.” Former Section 12901 did not include a definition for the term “medium” which was used in that regulation. • The proposed regulation is intended to encourage businesses to routinely test their discharges, releases and exposures so that they can assure compliance with the statutory requirements. OEHHA assumes that these companies should have direct access to their facilities, processes and products and should be in a position to collect and analyze samples.

APPENDIX 2 (Continued)

COMMENT NO.	COMMENTS & AFFILIATION	COMMENT	RESPONSE
PH-5 (continued)	Andrew L. Packard	<p>intermittent discharges or exposures?”</p> <ul style="list-style-type: none"> • Section 12900(a)(3), “that the method of detection and analysis was conducted by a laboratory certified by the State of California.” Lacks sufficient specificity. Labs may be certified to conduct wide variety of analyses, but may not be certified to perform the method of analysis at issue. • Recommended language: <i>“That the method of detection and analysis was conducted by a laboratory certified by the State of California to perform the particular method of detection and analysis in question.”</i> • Section 12900(a)(4), “that all the reported results show that the chemical in question was not detected.” Fails to specify that detection limits for the tests in question must be relevant to the discharge or exposure in question. • Recommended language: <i>“That all the reported results show that the chemical in question was not detected at levels relevant to the particular exposure or discharge scenario in question.”</i> 	<ul style="list-style-type: none"> • On the other hand, as stated in subsection (e) of the proposed regulation, if defendant does not assert the affirmative defense, plaintiffs may offer any admissible evidence to prove a violation of the Act. This would include the use of a proxy test medium where it is not possible to conduct a test using an identical sample. If defendant does assert the defense provided in the proposed regulation, plaintiff is free to challenge defendant’s compliance with any provision of the proposed regulation as it applies to the specific facts at issue. • OEHHA agrees with the commenter and has added the proposed language to the regulation. • This comment does not address the changes to the proposed regulation that are the subject of this notice. The proposed regulation is narrowly focused on situations in which testing has been performed and the test results indicate the chemical in question has not been detected. If the chemical has been

APPENDIX 2 (Continued)

COMMENT NO.	COMMENTS & AFFILIATION	COMMENT	RESPONSE
PH-5 (continued)	Andrew L. Packard	<ul style="list-style-type: none"> • Section 12900(b), “the method of detection and analysis that may be relied on for purposes of subsection (a) are those that are required or sanctioned by the Federal Food and Drug Administration, the USEPA...” Phrase, “required or sanctioned” is not subject to uniform interpretation. Concept of borrowing test methods used or referenced by other agencies in other contexts has proven unworkable. • Section 12900(g)(1), ““method of detection and analysis” means a specific analytical testing procedure appropriate for detecting a particular chemical in a particular matrix such as air, water, soil or food that is applied for the purpose of detecting the chemical or measuring its concentration. Phrase, “detection and analysis” broadens the concept of detection to diverse analyses. Phrase “particular medium” must be clarified for reasons discussed above. • P65 applies to an extremely diverse set of discharge and exposure scenarios. Only a court applying the existing rules of evidence can assess whether a test method is appropriate and relevant to a particular set of facts. • Section 12900(g)(3), “the phrase, “required or sanctioned” means that an agency listed in subsection (b) has identified the method of detection and analysis in a permit (as defined below), regulation, guideline or other official action of the agency that specifies or requires the use of that method of detection and analysis for purposes of detecting or measuring the concentration of the chemicals in question in the relevant matrix.” Phrase “for purposes of detecting or measuring the concentration of the chemical in question in the relevant matrix” suffers from the same problems as the use of the term “specific 	<p>detected, other regulations should be used to determine if any violation of the discharge or warning provisions of the Act has occurred.</p> <ul style="list-style-type: none"> • OEHHA has attempted to add clarity to the proposed regulation by including a definition for the phrase “required or sanctioned.” Former Section 12901 did not include a definition for the phrase “adopted or employed” which was used in that regulation. OEHHA believes this will assist courts and the businesses in determining which test methods may be used in a particular situation. It is not feasible for OEHHA to identify each method that might be appropriate for each chemical and type of discharge release or exposure scenario. Use of methods required or sanctioned by other agencies to detect and measure such chemicals is an appropriate alternative. • Courts are free to apply the existing rules of evidence in particular cases. The proposed regulation simply establishes the parameters for the assertion of an affirmative defense in certain circumstances.

APPENDIX 2 (Continued)

COMMENT NO.	COMMENTS & AFFILIATION	COMMENT	RESPONSE
PH-5 (continued)	Andrew L. Packard	<p>medium” in repealed Section 12901. May one use a method of detection that employs a proxy medium? Language does not permit evidence by inference, which is in conflict with the CA Evidence Code.</p> <ul style="list-style-type: none"> • Section 12900(g)(1) is clear that method of analysis may be used to “detect the chemical <u>or</u> measure its concentration.” (Emphasis added.) Section 12900(g)(3) fails to distinguish between “detecting or measuring,” which may give rise to conflict interpretations. • Recommended language: “...<i>for the purpose of detecting the chemical or measuring its concentration.</i>” 	<ul style="list-style-type: none"> • The wording change “...<i>for the purpose of detecting the chemical or measuring its concentration.</i>” proposed in this comment has been incorporated in the proposed regulation in subsection (g)(1).